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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,283	04/20/2006	Teruo Sugawara	472325006	5242

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WASHINGTON, DC 20005-1209

EXAMINER
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LONG, SCOTT

ART UNIT	PAPER NUMBER
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1633

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/565,283	<b>Applicant(s)</b> SUGAWARA, TERUO	
	<b>Examiner</b> Scott D. Long	<b>Art Unit</b> 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 5 and 6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5, and 6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

*The examiner acknowledges receipt of claim amendments and applicant's remarks, filed 13 September 2007.*

### ***Claim Status***

Claims 1-2 are amended. Claims 3-4 are cancelled. Claims 5-6 are newly submitted. Claims 1-2 and 5-6 are under current examination.

### ***Priority***

This application claims as a 371 of PCT/JP04/03449 (filed 03/15/2004). This application also claims benefit from foreign application, JAPAN 2003278429 (filed 07/23/2003). The applicant correctly cites MPEP 201.15, which indicates that a translation of a foreign priority document is only required if an applicant relies on the priority document to overcome a rejection made by the Office. Accordingly, the instant application has been granted the benefit date, 23 July 2003, from the foreign application JAPAN 2003278429.

***Response to Arguments - Claim Rejections 35 USC § 112***

*Response to Arguments – 35 USC 112, second paragraph*

Applicant's arguments, see page 6 and Claim amendments, filed 13 September 2007, with respect to claims 1-4 have been fully considered and are persuasive.

Claims 3-4 are cancelled. Therefore, the rejections of claims 3-4 under 35 USC 112, second paragraph, have been made moot by the claim amendments submitted on 13 September 2007 and are hereby withdrawn.

The applicant's arguments regarding the definition of "substantially identical to" as recited in the specification on page 4, lines 6-10, are sufficient to overcome the applicant's rejection of 1-2 under 35 USC 112, second paragraph. Therefore, rejection of claims 1-2 under 35 USC 112, second paragraph is hereby withdrawn.

*Response to Arguments – ENABLEMENT (35 USC 112, first paragraph)*

Applicant's arguments (pages 7-8) filed 13 September 2007 have been fully considered and they are persuasive. Claims 3-4 are cancelled. Therefore, the rejection of claims 3-4 under 35 USC 112, 1<sup>st</sup> paragraph is moot. The examiner hereby withdraws the rejection of claims 3-4 under 35 USC 112, 1<sup>st</sup> paragraph.

## **NEW GROUNDS OF REJECTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation "said oligonucleotide" in line three. There is insufficient antecedent basis for this limitation in the claim. Claim 2, as amended is directed to a double stranded RNA, but there is no mention of oligoribonucleotide in claim 2 and it is not clear to which oligoribonucleotide the phrase "said oligoribonucleotide" of claim 2 refers in claim 1.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **THIS IS A NEW MATTER REJECTION.**

The kit of claim 6 recites "a component useful for introducing the oligoribonucleotide" in line 4 of claim 6. The specification contains no mention of the phrase "a component useful for introducing the oligoribonucleotide." What is this component? While the specification describes the kit as comprising the oligoribonucleotides and "a means to introduce into cancer cells" (page 3, line 2), such means might encompass electroporation, which has no components. Therefore, the examiner concludes that claim 6 introduces new matter.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Chew et al (WO2001/04137, published 18 January 2001).

Claim 1, as amended, no longer limits the size of the oligoribonucleotides to "containing" bases 187-205 or bases 474-494 of SEQ ID NO:1, while also being less than 23 contiguous nucleotides. The currently amended claim requires that the oligoribonucleotide must be "substantially identical to" less than 23 contiguous nucleotides of SEQ ID NO:1 and "target bases 187-205 or bases 474-494 of SEQ ID

Art Unit: 1633

NO:1.” Since the term, “target,” is not explicitly defined in the specification, the examiner is interpreting the claim to mean that any oligoribonucleotide which is identical to or a complement of a portion of bases 187-205 or bases 474-494 of SEQ ID NO:1 and is less than 23 contiguous nucleotides satisfies the limitations of claim 1. Chew et al. teach, an oligonucleotide, SEQ ID NO:184 (GATGTTTCCA), which is 100% identical to bases 189-198 of SEQ ID NO:1. Chew et al. also teach, “the oligonucleotide may be comprised of any phosphorylation state of ribonucleotides, deoxyribonucleotides” (page 19, lines 35-36).

Accordingly, the teachings of Chew et al. anticipated the instant claim.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 5 are rejected under 35 U.S.C. 103(a) as being obvious over Wang et al (US2003/01655949, published 4 September 2003).

Claim 1, as amended, no longer limits the size of the oligoribonucleotides to “containing” bases 187-205 or bases 474-494 of SEQ ID NO:1, while also being less than 23 contiguous nucleotides. The currently amended claim requires that the

Art Unit: 1633

oligoribonucleotide must be "substantially identical to" less than 23 contiguous nucleotides of SEQ ID NO:1 and "target bases 187-205 or bases 474-494 of SEQ ID NO:1." Since the term, "target," is not explicitly defined in the specification, the examiner is interpreting the claim to mean that any oligoribonucleotide which is identical to or a complement of a portion of bases 187-205 or bases 474-494 of SEQ ID NO:1 and is less than 23 contiguous nucleotides satisfies the limitations of claim 1. Wang et al. teach SEQ ID NO:142 (GATGTTTCCA) which is 100% identical to bases 189-198 of SEQ ID NO:1 of the instant application. Wang et al. teach, "the term 'nucleic acid' as used herein also includes antisense nucleic acids." Wang et al. also teach RNAi (parag.0187) and "nucleic acid probes can be...any RNA-like or DNA-like material" (parag.0110).

Claim 5 is directed to a method for inhibiting expression of SBP gene in cancer cells, comprising introducing into cancer cells in vitro the sense oligoribonucleotide, the antisense oligoribonucleotide or the double stranded RNA comprised thereof as in claim 1. Wang et al. teach, *ex vivo* treatment of bone marrow samples of individuals having myeloid leukemia "employing a composition comprising any sequence set forth in SEQ ID NOs:1-244" (page 15, parag.0153).

It would have been predictably obvious to the person of ordinary skill in the art at the time of the invention was made to use SEQ ID NO:142 as taught by Wang et al. in an *ex vivo* treatment of cancer cells.

The person of ordinary skill in the art would have been motivated to use an oligoribonucleotide form of SEQ ID NO:142 or an antisense oligoribonucleotide



Art Unit: 1633

complimentary to SEQ ID NO:142, because Wang et al. teach that their ex vivo approaches could utilize any form of RNA, including complementary and antisense nucleic acids.

Therefore the method as taught by Wang et al. would have been *prima facie* obvious over the method of the instant application.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims are allowed.

***Examiner Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**.

The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Scott Long  
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JLE